IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): James H. Aylward

Examiner: C. Tate

Serial No: 09/888,997

Art Unit: 1654

Filed: June 21, 2001

Docket: 14923A

For: METHOD OF STIMULATING THE IMMUNE SYSTEM

Dated: September 26, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Sir:

In response to the Office Action dated March 26, 2003, applicant submits the following Amendment for entry in the above-identified case. The amendment to the claims is reflected in the listing of the claims hereinbelow.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450 on **September 26, 2003**.

Dated: September 26, 2003

Mark J. Cohen

II. Claims 78-81, drawn to a method of stimulating the immune system via administering an effective amount of at least two compounds, classified in class 514, subclass 100+.

III. Claims 93-95, drawn to a method of recruiting an immune cell to a region of application of an undefined compound by administering the undefined compound to the region, classified in class 424, subclass 725, for example."

In support of the Restriction Requirement, the Office Action alleges that the method of Group I requires the administration of one active compound ("from among numerous distinct compounds recited therein") and that the method of Group II requires the administration of a combination of two or more active compounds. Furthermore, according to the Office Action, the practice of Group II does not necessarily include the use of any one compound of Group I. The Office Action further alleges that the method of Group III is drawn to administration of an "undefined compound" (e.g., plant extract) which does not necessarily include any of the compounds of Groups I or II and further is directed to a different functional effect than that of Groups I and II. According to the Office Action, one would not have to practice the various methods at the same time to practice just one method alone.

In addition, the Office Action has requested applicants to elect a species if Group I is elected or two or more species if Group II is elected.

In order to be responsive, applicant elects, with traverse, the subject matter of Group I, i.e., Claims 33-77 and 82-92 for continued prosecution herein. Moreover, in order to be responsive to the election of species requirement, applicant elects Group D, that is, the

be responsive to the election of species requirement, applicant elects Group D, that is, the method of stimulating the immune system using an angeloyl-substituted ingenane compound or derivative or salt thereof. Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter.

Nevertheless, applicant hereby traverses, pursuant to 37 C.F.R. §§1.111 and 1.143, the requirement for restriction and requests reconsideration thereof in view of the following remarks.

Applicant respectfully requests that the Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. §121 and 37 C.F.R. §§1.141 - 1.142.

35 U.S.C. §121 provides that the Commissioner may restrict an application when two or more independent and distinct inventions are claimed in a single application. (Emphasis added). Similarly, 37 C.F.R. §1.141(a) permits restriction conditioned upon a finding that independent and distinct inventions are found within one application. Applicant respectfully submits that the Office Action has not made out a prima facie case to support a restriction requirement between Groups I-III for it has not shown that Groups I-III are independent.

Only the statutory requirement that the claims of the various groups are distinct from each other has been proffered as the basis for the requirement of restriction between Groups I, II and III. Even assuming, pro arguendo, that the Office Action is correct with respect to distinctiveness, there is absolutely no indication in the Office Action that Groups I, II and III are also independent. In fact, Applicant submits that there is interdependence between each alleged group of claims.

MPEP §802.01 defines independent as follows:

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect...

Applicant respectfully submits that the subject matters in Groups I, II and III are "connected in design, operation or effect" and are thus not independent.

The subject matter of all of the claims is related to the administration to a subject of an effective amount of at least compound derived from the sap of a species of Euphorbia, wherein the compound

(a) is extractable from the Euphorbia sap in the presence of about 95% v/w ethanol,

(b) has cell inhibiting or retarding activity which is neither destroyed by acetone nor by heating at about 95°C for about 15 minutes, and

(c) is capable of inhibiting the growth of at least one cell line selected from the group consisting of MM96L, MM229, MM220, MM537, MM2058, HeLa, B16, LIM1215, A549, MCF7, MCC16 and Colo16. Examples of compounds that fit this description include the jatrophane compound, pepluane compound, paraliane compound and angeloyl-substituted ingenane compound or derivatives or salts of any of the aforementioned compounds.

Thus the subject matter in Groups I, II and III have a disclosed relationship since they fit the description provided hereinabove. Since the Office Action has not alleged the statutory required independence of the groups and further because these groups of claims are connected in design, operation and/or effect, and are therefore not independent, the claims which the Office Action has grouped separately are not "independent and distinct" so as to justify the restriction requirement. It is therefore respectfully submitted that the Restriction Requirement is improper and cannot be maintained.

Moreover, with respect to the election of species requirement, and the allegation that the application contains four patentably distinct species - - (a) the jatrophane compound or derivative or salt thereof, (b) the pepulane compound or salt or derivative thereof, (c) paraliane compound or salt or derivative thereof or (d) an the angelolyl-substituted ingenane compound or salt or derivative thereof - - applicant respectfully submits that the United States Patent and Trademark Office has not made out a prima facie case.

In accordance with MPEP §808, "every requirement to restrict has two aspects": (A) the reasons (as distinguished from the mere statement of conclusion) why the inventions as claimed are either independent or distinct and (B) the reason for insisting upon restriction therebetween.

With respect to the election of species requirement, the United States Patent and Trademark Office has not provided any reasons that the various compounds recited in Groups A-D are patentably distinct. It just makes a mere statement of conclusion without providing any rationale or evidence in support thereof. It did not provide any reasons why the various alleged inventions in Groups A-D as claimed are independent and/or distinct nor did it provide the reasons for insisting upon restriction therebetween. Moreover, contrary to the allegations of the Office Action, there is a disclosed relationship between the various compounds, for example, they all fit the description recited in Claim 1. Thus, the election of species requirement is improper and should be withdrawn.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicant has done herein, so as to encourage applicants to provide a more detailed disclosure of all aspects of their invention. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

Applicant respectfully suggests that in view of the continued increase of official fees and the potential limitation of applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravenes the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), the applicant is required to either conduct simultaneous prosecution with attendant filing fees and costs or face a compromise of the term of his patent assets.

Then, it is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon does not provide comfort against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention-double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), that court held that §121 does not insulate a patentee from an allegation

of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicant respectfully urges the Examiner not to require restriction in cases such as the present application.

Applicant further submits that with respect to the Restriction Requirement between Groups I and II, the Restriction Requirement is improper for additional reasons. As indicated hereinabove, there is a disclosed relationship between the subject matter of Groups A, B, C and D. Since the United States Patent and Trademark Office has not showed that Groups A, B, C and D are patentably distinct, it thus follows that a claim comprising one or more compounds falling within the scope of Claim 1 is generally considered to represent the same invention as that of Claim 1. However, the subject matter of Claims 78-81 is directed to the use of the combination of at least two compounds falling within the scope of Claim 1. Since each compound falling within the scope of Claim 1 represents one invention, the combination also represents one invention. Thus, to that extent that the Office Action imposes a restriction requirement between the use of one compound falling within the scope

of Claim 1 (Group I) and two or more compounds falling within the scope of Claim 1 (Group II), such Restriction Requirement is improper and should be withdrawn.

Applicant respectfully submits that the present restriction requirement between Groups I and II is not proper for still another reason; the groupings of the claims are not in compliance with the MPEP. Contrary to the allegations in the Office Action, the subject matter of Groups I and II have the same classification (Class 514, subclass 100+). Moreover, they do not have a different field of search, nor is there any showing that they have a different field of search. Further, there is no clear identification of separate future classification or field of search. Under these circumstances, according to the MPEP, no reasons exist for dividing among the related invention. MPEP §808.02. Thus, in accordance with MPEP §808.02, there should be no restriction imposed between Groups I and II, especially since there is no additional burden imposed upon the Examiner in searching the subject matter of Group I and Group II. Consequently, inasmuch as the restriction requirement is not in conformance with the MPEP, the applicant respectfully submits that for still another reason, the restriction requirement should be withdrawn.

Hence, it is respectfully requested that the United States Patent and Trademark Office reconsider and withdraw the requirement for restriction pursuant to 35 U.S.C. §121 and provide an action on the merits with respect to all of the claimed subject matter.

Respectfully submitted,

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